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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,826	10/29/2003	James C. Kennedy	67286-278	2825
22428	7590	10/12/2005	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			SHARAREH, SHAHNAM J	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/605,826	Applicant(s) KENNEDY ET AL.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/29/2003, 9/13/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/26/04, 8/24/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's election without traverse of Group I in reply filed on September 13, 2005 is acknowledged.

Claims 2 and 3-21 in part are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant has further failed to elect a species directed to 5-aminolevulinic acid ("5-ALA") and a wavelength of light between 350-640 nm.

The claims to the extent that they read on the elected species are allowed accordingly.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The second application (which is called a continuing application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the continuing application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *In re Ahlbrecht*, 168 USPQ 293 (CCPA 1971).

2. In the instant case, the invention as a whole (ie, including limitations set forth in dependent claims) is fully 09/293,835 filed on April 19, 1999.

The grandparent applications do not sufficiently disclose the entire scope of the instantly claimed methods of treating non-malignant skin lesions comprising administering to a patient a precursor of protoporphyrin IX and exposing the site to wavelengths of about 350-700 nanometer or all types of non-malignant skin disorders to the extent sufficient to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention has proper written description in the grandparent application SN 07/386,414, now US Patent 5,079,262, filed on July 28, 1989 for methods of treating non-malignant hyperproliferative skin lesions comprising administering 5-ALA and the wavelength of light between 350-640 to a patient. Accordingly, the claims are directed to such conditions

With respect to the entire genus of non-malignant skin lesions and application of wavelengths of upto 700 nm, the application has the effective priority date of April 19, 1999.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 3-21 are rejected under the judicially created doctrine of double patenting over claims 1-12 of US Patent 6,710,066, claims 1-12 of U. S. Patent No.

5,955,490, and claims 1-2 of US Patent No. 5,211,938; since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are directed to methods of treating skin conditions comprising the same process steps as instantly claimed. Therefore, the instant claims are an obvious variant of the patented claims; because one of ordinary skill in the art would have had a reasonable expectation of success in practicing the same process steps in treating a skin lesion as treating acne or skin lesions caused by a bacterium.

4. Claims of US Patent 6,710,066 are directed to the same process steps and thus it would have been obvious to one of ordinary skill in the art at the time of invention to practice the scope of the instant claims one in possession of the patented claims.

5. Claims of US Patent 5,955,490 are directed to the same process steps and thus it would have been obvious to one of ordinary skill in the art at the time of invention to practice the scope of the instant claims one in possession of the patented claims.

6. Claims of US Patent 5,211,938 are directed to the same process steps and thus it would have been obvious to one of ordinary skill in the art at the time of invention to practice the scope of the instant claims one in possession of the patented claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Richter et al US Patent 5,705,518.

Richter discloses methods of treating skin lesions administering an effective amount of photosensitizing agents and activating them via a light source (abstract, col 7, lines 45-67, example 1, claim 1, 5). Richter's compounds are benzoporphyrin derivatives (BPD) which do not exert their activities through synthesis of 5-aminolevulinic acid (5 ALA), thus they bypass the synthesis of 5 ALA. Accordingly, Richter anticipates the limitations of the instant claims.

8. Claims 1, 6, 7-16, 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Bommer US Patent 4,977,177..

Bommer is merely used to show that topical administration of protoporphyrin derivatives is conventional. Specifically, Bommer is cited to establish that porphyrin derivatives are art recognized equivalents to the extent they are prepared in topical pharmaceutical dosage forms. Bommer, for example, teaches that various porphyrin related compounds including protoporphyrin IX and its prodrugs can be used topically in a cream form having suitable pharmaceutical carriers (see table I, claims 1, 16, 23, 30, 37, 41; col 12, lines 7-30). Accordingly, topical use of porphyrin prodrugs is well established in the art.

9. Claims 1, 4-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Divaris et al (American Journal of Pathology, vol 136, no. 4, april 1990). .

Divaris discloses methods of treating skin lesions and hair follicles administering an effective amount of 5-ALA and activating them via a light source (abstract, pages 891-892, 896). Divaris compounds are precursors of protoporphyrin IX. Accordingly, Divaris anticipates the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 3-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al US Patent 5,705,518 in view of Bommer US Patent or 4,977,177.

The instant claims appear to be directed towards a method of treating non-malignant skin lesions comprising administering a precursor of protoporphyrin IX and further exposing the agent to light capable of photo activating protoporphyrin IX.

Richter teaches that photosensitizing agents such as BPD derivatives for treatment of skin lesions. Richter further states that protoporphyrin prodrugs such as 5-aminolevulinic acid can also be used to treat non-malignant lesions such as those caused by warts or psoriasis (see col 4, lines 49-65; col 5, lines 50-65; col 10, lines 56-60). Richter also teaches that said photosensitizing agents could be administered topically via patches or implants (col 6, lines 6-21). Thus, Richter teaches the limitations of the instant claims except that it does not explicitly administer a protoporphyrin prodrug topically.

Bommer is merely used to show that topical administration of protoporphyrin derivatives is conventional. Specifically, Bommer is cited to establish that porphyrin derivatives are art recognized equivalents to the extent they are prepared in topical pharmaceutical dosage forms. Bommer, for example, teaches that various porphyrin related compounds including protoporphyrin IX and its prodrugs can be used topically in a cream form having suitable pharmaceutical carriers (see table I, claims 1, 16, 23, 30, 37, 41; col 12, lines 7-30). Accordingly, topical use of porphyrin prodrugs is well established in the art.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use 5-aminolevulinic acid topically, as suggested by Richter, for the purposes of treating non-malignant skin lesions, because it is well known in the art that porphyrin derivatives including porphyrin prodrugs, such as 5-aminolevulinic acid, can be used topically for their desired therapeutic result. The ordinary skill in the art would have had a reasonable expectation of success because, as shown by Bommer, preparing a topical formulation of protoporphyrins and employing such compounds topically is conventionally achieved.

11. Claims 1, 3-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pandey US Patent 5,093,349.

Pandey teaches methods of treating skin tumors comprising topically administering to a patient dimers of deuteroporphyrins or hydrophobic esters thereof which are derivatives of protoporphyrin-IX. (see abstract) Pandey further administers light to the site of interest. (see col 10-11, specifically col 11, lines 1, 32-39). Pandey's

compounds are hexy ethers of a tetrapyrrole. There is no indication that such compounds are photosensitive themselves outside a body. Further, since such compounds are hydrolyzed to protoporphyrin, they are viewed to induce the synthesis of such compound in vivo.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to practice the scope of the instant claims by Pandey's methodologies, because as taught by Pandey, other esters or dimers of protoporphyrin are suitable for treating skin lesions.

Conclusion

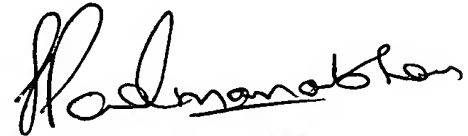
12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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